

Quantification of prosthetic outcomes: Elastomeric gel liner with locking pin suspension versus polyethylene foam liner with neoprene sleeve suspension

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H1

Appendix A

H1

Summary of Literature on Key Issues for Elastomeric Suspension Liners in Lower Limb Prosthetics

This summary of peer-reviewed literature is organized by clinical issue pertaining to the use of elastomeric suspension liners in lower limb prosthetics. It is important to note that there are differences between the various systems, including composition of the gel material (silicone vs. other elastomer), contouring, tapering, and thickness of the liner, suspension method, presence or absence of an outer cover over the liner, and recommended socket design. Similarities between the systems include enclosed environment of the residual limb, mechanical action of the liner on the limb, requirements for donning and doffing (somewhat variable), and requirements for hygiene and maintenance.

H2

Suspension

Most studies have reported that elastomeric suspension liners provide improved suspension. Cluitmans et al. [1] reported that all subjects felt suspension with the ICEROSS (silicone gel) system [2] to be better than that of their previous prosthesis. Hachisuka et al. [3] found positive questionnaire responses to “piston movement during walking,” “ease to swing the prosthesis,” and “comfort to wear” were significantly related to a rating of “satisfied” or “somewhat satisfied” with the Silicone Suction Socket (3S) system. Lake and Supan [4] reported that silicone liners provided a superior form of suspension with minimal pistoning that gave users a feeling of secure suspension. Hatfield and Morrison [5] found that 25 percent of 40 subjects who had been prescribed Alpha® locking liners in routine clinical practice reported improved suspension relative to their previous prosthesis.

Narita et al. [6] used static x-ray and dynamic cineradiography to measure the suspension effect of TSB sockets with ICEROSS locking liners versus PTB sockets. They quantified statistically significant improvements with the ICEROSS condition. Dasgupta et

al. [7] reported better scores in task-oriented tests with the ICEROSS system and attributed the change to improved suspension.

In a survey of 72 doctors and prosthetists in the United Kingdom, McCurdie et al. [8] found suspension to be the leading “absolute” or “primary” indicator for ICEROSS prescription. Pistoning, lack of success with other forms of suspension, and need for improved suspension due to change in type or level of activity were seen as clear indicators for ICEROSS use.

H2

Skin Irritation, Perspiration, Hygiene

Skin irritation, itching, and perspiration have been reported as problematic with elastomeric liners almost universally. Cluitmans et al. [1] found that of 26 subjects who had experienced a different type of prosthesis, 42 percent reported an increase in perspiration, 46 percent an increase in itching, and 31 percent an increase in soreness with the ICEROSS prosthesis. The researchers noted that itching and/or perspiration with the ICEROSS system tended to diminish markedly after some weeks or months, but compared with subjects' previous prostheses, “distinct problems remained.” Datta et al. [9] found that new ICEROSS users reported significantly increased perspiration in the first three weeks that “settled” thereafter. Their subjects also reported a decrease in skin breakdown with the ICEROSS system.

Of 13 subjects using the 3S locking pin liner, Hachisuka et al. [3] reported that skin irritation was rated as “good” or “somewhat good” by more than 75 percent. Perspiration was rated as “poor” or “somewhat poor” in approximately 25 percent of subjects. Perspiration decreased with time, but was still problematic. In a later study, Hachisuka [10] investigated the relationship between washing of the residual limb and silicone liners (ICEROSS, 3S, Fillauer Silicone Suspension Liner) with the incidence of skin problems and perspiration. The subjects ($n = 83$) experienced problems with itching (60%), perspiration (47%), eruption (46%), and odor (43%). These events were reduced by daily washing, but remained problematic. Boonstra et al. [11] found that five of six subjects reported more perspiration with a Pe-Lite™ system than with a 3S system; five of six subjects complained of extreme perspiration prior to enrollment.

Lake and Supan [4] investigated skin problems in 56 persons with transtibial or transfemoral amputation who wore silicone suspension liners, and noted that, while nearly all practiced good hygiene, skin irritation persisted. The incidence of skin problems reduced with increased age (they suggest due to decreased perspiration) and was lower in persons with amputation of vascular versus traumatic origin (they suggest as a function of age and/or activity level). The use of a sheath between the liner and skin decreased the incidence of contact dermatitis and folliculitis, while the use of powders increased contact dermatitis. Interestingly, the researchers found the incidence of skin problems to be greater in persons switching to silicone systems from other systems (versus going directly to a silicone system after amputation), but to increase with years of use of silicone systems.

McCurdie et al. [8] found that clinicians polled in the United Kingdom felt poor patient hygiene was a clear contraindicator for ICEROSS prescription, and noted that respondents commented on the frequency with which skin problems were encountered with this system. They mention that their sample held “diametrically opposed views” on the

advisability of ICEROSS prescription for patients with issues such as stump skin breakdown, neuropathic/insensitive skin, shear-sensitive skin, and split skin grafts.

H2

Walking/Mobility

Hachisuka et al. [3] reported that out of 32 subjects, over 90 percent rated walking as “good” or “somewhat good” with the 3S system. Dasgupta et al. [7] studied 27 subjects and found statistically significant improvements in timed walks with ICEROSS systems.

In a study of 54 persons, Datta et al. [9] found that subjects did not report walking more, having greater ease negotiating uneven surfaces, reducing the use of mobility aids or wearing the prosthesis more with the ICEROSS prosthesis compared to previously worn PTB prostheses.

H2

Appearance/Cosmesis

Dasgupta et al. [7] and Lake and Supan [4] reported improvements in cosmesis with elastomeric suspension systems with distal locking pins. Hachisuka et al. [3] found that approximately 95 percent of subjects in the 3S system rated appearance as “good” or “somewhat good.” Cluitmans et al. [1] noted a decrease in satisfaction with cosmesis due to the visibility of the cord used in the particular ICEROSS suspension system they studied.

H2

Donning and Doffing

Hachisuka et al. [3] found “donning and doffing of the prosthesis” was significantly related to a rating of “dissatisfied” or “somewhat dissatisfied” with the 3S system, and was rated as “good” by fewer than 40 percent of subjects. Cluitmans et al. [1] noted that some subjects considered donning and doffing time to be problematic for night use when they needed to use the toilet. Lake and Supan [4] listed poor cognitive capacity and compromised hand function as factors posing problems for donning which contraindicate use of silicone suspension liners.

H2

Satisfaction

Hachisuka et al. [3] reported that 50 percent of subjects were “satisfied” with the 3S TSB socket system and 25 percent were “somewhat satisfied.” “comfort to wear,” “ease to swing the prosthesis,” and “piston movement during walking” were related to a rating of “satisfied” or “somewhat satisfied.” Hatfield and Morrison [5] found that 50 percent of subjects switching to Alpha® locking liners reported improved comfort relative to their previous system, but the researchers did not report overall satisfaction. Datta et al. [9] found a 22 percent higher overall rating by subjects for the ICEROSS TSB prosthesis versus the previously used PTB prosthesis.

H2

Rejection Rate

Dasgupta et al. [7] found an overall rejection rate of 37 percent in subjects they followed who had been provided an ICEROSS prostheses. Datta et al. [9] found a rejection rate of 27.7 percent with subjects who had been prescribed the ICEROSS suspension system after using a PTB system. Two-thirds of rejections were due to skin problems. Based on the rejection rate, they suggested the ICEROSS system may not be suitable as a standard prosthesis for all amputees. Boonstra et al. [11] experienced a 25 percent dropout rate due to rejection of the 3S liner in their crossover study. Hatfield and Morrison [5] found a rejection rate of 20 percent in subjects they followed who had been prescribed Alpha® locking liners. They recommended that careful selection of patients and detailed discussions about the possible benefits and disadvantages of the system was essential to ensure maximum benefit and to avoid the costs of inappropriate prescription. The study designs of Cluitmans et al. [1] and Hachisuka et al. [3] did not permit assessment of rejection rate.

HI

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